



Specified Animal Pathogens Order (SAPO) Licences

1. Introduction

This guidance is provided to help you understand basic requirements for work with designated pathogens and related materials which are controlled under the Specified Animal Pathogens Orders (SAPO). Specified animal pathogens are infectious agents, such as viruses, bacteria and parasites. The purpose of SAPO is to prevent the introduction and spread into this country of these specified animal pathogens which if introduced could cause serious disease and economic loss. Any work with SAPO pathogens or related materials requires that a risk assessment is carried out and a SAPO licence must be obtained by Schools from the Health and Safety Executive.

2. Guidance Sources for Specified Animal Pathogens Order (SAPO) Licences

There is regulatory guidance and information on control of work with specified animal pathogens which is available from the Health and Safety Executive (HSE) and Animal Health which can be found below.

2.1 Guidance

- [HSE Containment and control of specified animal pathogens](#)
- [HSE ACDP Approved list of biological agents](#)
- [HSE ACDP Management and operation of microbiological containment laboratories](#)
- [HSE SACGM Compendium of guidance](#)

2.2 Websites

- [HSE Specified Animal Pathogens](#)
- [Animal Health \(Scotland\)](#)
- [Animal and Plant Health Agency](#)
- [World Organisation for Animal Health](#)

3. SAPO Risk Assessment and Licences

SAPO requires certain controls to protect the economy, agriculture, food and the environment from serious animal infectious diseases caused by introduction or exposure of these designated pathogens or related materials in which they may be carried or transmitted. The general requirements for risk control of work involving specified animal pathogens are set out in the HSE guidance for licence holders on the containment and control of specified animal pathogens and are detailed on the HSE SAPO website.



- [HSE Containment and control of specified animal pathogens](#)
- [HSE Specified Animal Pathogens](#)

Remember that compliance with the controls for work with biological agents and genetically modified organisms may also be required to protect people and the environment.

3.1 Specified Animal Pathogens

The designated animal pathogens and related materials which are controlled under SAPO are defined below.

A 'specified animal pathogen' means an animal pathogen listed in Schedule 1 of SAPO.

- Intact pathogens.
- Pathogens which have been attenuated or genetically modified by any means.
- Any nucleic acid derived from an animal pathogen listed in the Schedule which could produce that pathogen when introduced into a biological system in which the nucleic acid is capable of replicating.

A 'carrier' means any living creature, except man, which may carry or transmit a specified animal pathogen or the tissue, cell culture, body fluid, excreta, carcass or part of a carcass of such creature by or by means of which a specified animal pathogen may be transmitted.

'Notifiable' diseases are animal diseases that must be reported to the Animal and Plant Health Agency (APHA). Notifiable diseases can be endemic, already present in the UK, or exotic and not normally present in the UK. Some endemic and exotic diseases are zoonotic which means they can spread between animals and humans.

3.2 Classification of SAPO Pathogens

SAPO pathogens are classified into one of four groups based on their risks to the economy, agriculture, food and the environment.

- **Group 1:** Disease-producing organisms which are enzootic (native in animals in this country) and do not produce notifiable disease.
- **Group 2:** Disease-producing organisms which are either exotic or produce notifiable disease, but have a low risk of spread from the laboratory.
- **Group 3:** Disease-producing organisms which are either exotic or produce notifiable disease and have a moderate risk of spread from the laboratory.
- **Group 4:** Disease-producing organisms which are either exotic or produce notifiable disease and have a high risk of spread from the laboratory.

SAPO only applies to groups 2, 3 and 4 specified animal pathogens and these require a SAPO licence before they can be possessed or used. There is a defined list of SAPO



pathogens which is published on the HSE SAPO website and in the guidance, although it is also the case that other relevant unlisted animal pathogens could also be covered by the legislation and require a SAPO licence. Note that a pathogen may be classified under COSHH as well as SAPO although the hazard groups may be different in each system.

3.3 SAPO Risk Assessments

A BA / GM risk assessment should be carried out for all work involving specified animal pathogens and related materials. These SAPO risk assessment should deal with the scope and risks of the specific work activities and the pathogens and other designated materials involved and must determine what containment and control measures are required to enable the work to be done safely. The principles and requirements for risk control of work involving specified animal pathogens are set out in the HSE guidance for licence holders on the containment and control of specified animal pathogens.

If the work involves biological agents or genetically modified organisms then compliance with the controls for these will also be required to protect humans and the environment. Some SAPO pathogens can cause diseases that are zoonotic which means they can spread between animals and humans. There is guidance on BA and GM risk assessment, containment and control which is available on the Biosafety Unit website.

The SAPO risk assessments must be done in advance of the import, possession or use or licencing of any of the materials following the standard processes and they have to be reviewed and approved by the School GM and Biological Safety Committee (GMBS). The risk assessments must be amended in advance whenever this is needed such as for changes to the scope or risks of the work and the licences updated where required.

3.4 SAPO Containment and Control Measures

The containment and control measures required for SAPO work are determined by compliance with the relevant minimum legal standards, regulatory guidance, the outcomes of the specific risk assessments, SAPO licence conditions and any permitted derogations. The general requirements for risk control of work involving specified animal pathogens are set out in the HSE guidance for licence holders on the containment and control of specified animal pathogens and on the HSE SAPO website. SAPO requires containment and controls to be applied to prevent the introduction or spread of these serious animal infectious diseases caused by exposure to designated pathogens and to prevent any release into the environment. The minimum containment and control measures set out in the containment tables in the guidance are required to control the risk for each of the specified animal pathogens categorised into SAPO groups 2, 3 or 4. There are only SAPO containment levels 2 and 3 used here in laboratories and animal facilities since work with SAPO 4 pathogens or at SAPO containment level 4 is not permitted in the university.



- **Containment level 2 (CL 2)** is required for work involving SAPO group 2 pathogens and related materials.
- **Containment level 3 (CL 3)** for work involving SAPO group 3 pathogens and related materials.

The SAPO guidance provides four containment tables which detail the control measures that apply to different circumstances for use of specified animal pathogens. For each of the containment levels and related control measures listed in the containment tables, an indication is given as to whether the measure is 'required' or 'not required' for each of the containment levels. In some instances, the term 'required where and to extent the risk assessment shows it is required' is used, which means the control measure must only be applied if the risk assessment indicates that the measure is required. As well as the containment tables, guidance on each containment measure and its use is provided.

3.5 Derogations

The guidance provides details of the standard containment and control measures for work involving specified animal pathogens. The containment tables summarise the minimum containment conditions and related control measures which are normally required for each containment level. However in certain circumstances it may be acceptable to use less than the minimum containment and control conditions normally required subject to risk assessment and application to the regulator for a derogation during the licence application process.

3.6 SAPO Licences

SAPO prohibits any person from having in their possession any specified animal pathogen or any carrier in which they know such a pathogen is present. The possession or use of any of these controlled pathogens or materials requires a licence to be obtained. The guidance on the regulations that control work with specified animal pathogens and how to apply for a SAPO licence can be found on HSE SAPO website.

- [HSE Specified Animal Pathogens](#)

The key purpose of the licence is to ensure that appropriate, proportionate and effective containment and control measures are applied, to prevent the release or escape of specified animal pathogens into the environment where they may cause serious animal disease. A specified animal pathogen can only be held or used by those who have a SAPO licence, which contains a set of conditions that must be met, and have a suitable and sufficient risk assessment and standard operating procedures. The controls should be proportionate to the level of risk and complexity of the activities and must be set out in the BA / GM risk assessments for the work.

Licences must be fully implemented and all conditions and controls put in place and maintained. Licences can be amended where needed and changes must be notified



to HSE with a request for an amendment to the existing licence or else as a new licence application. Full details on the SAPO licence application processes are provided on the HSE website.

Note also that there are specific requirements for licences to be obtained to import into the UK any specified animal pathogens or related materials under the Importation of Animal Pathogens Order (IAPO) and details can be obtained from the APHA website.

- [Animal and Plant Health Agency](#)

3.7 Information, Training and Supervision

Managers must provide workers with the necessary information, instructions and training on the general and emergency procedures and be properly supervised to enable them to safely carry out their work.

3.8 Incident Reporting and Investigation

Any SAPO incident must be reported to the manager responsible for the work and as soon as practicable to the Health and Safety Department using the incident reporting system. Incidents should be investigated by Schools and managers to identify the root causes and especially to help prevent the recurrence of similar incidents. SAPO requires that certain types of incidents must be reported to HSE. The School and licence holder must notify the licensing authority immediately in the event of the following events.

- An accident or dangerous occurrence involving any of the specified animal pathogens.
- Loss of a specified animal pathogen during its transportation.
- Any other relevant event specified in the licence or regulatory conditions.

The incident reporting requirements under SAPO are separate from and in addition to any requirements under RIDDOR.

4. Biological Agents and Genetically Modified Organisms

If the work also involves any biological agents or genetically modified organisms then the requirements of the Control of Substances Hazardous to Health Regulations (COSHH) and or the Genetically Modified Organisms (Contained Use) Regulations (GMOCU) would have to be applied in addition to those required under the Specified Animal Pathogens Orders (SAPO) and the relevant licences. COSHH and GMOCU have requirements for risk assessment, containment and control measures. Note that a pathogen may be classified under COSHH as well as SAPO and where this is the case then the requirements of both systems must be followed. The classification systems are not the same and a pathogen for example may have a different grouping under SAPO than under COSHH. If multiple regimes apply then all requirements apply but where



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there are differences between them then highest standard of risk control must be implemented. There is guidance and information on safe working with pathogens and BA and GM risk assessment, containment and control available on the Biosafety Unit website. Please contact your School Biological Safety Adviser for advice if you are planning do any work with specified animal pathogens or related materials.

Document version

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V1.0	New template	June 2023 HE
V1.1	Minor updates to text and links	January 2024 PH

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